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November 6, 2003

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

BILLSTEIN ET AL.

APPLICATION NO: Not Yet Assigned

FILED: Herewith

FOR: PHARMACEUTICAL COMBINATIONS AND THEIR USE IN
TREATING GASTROINTESTINAL AND ABDOMINAL VISCERA
DISORDERS

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

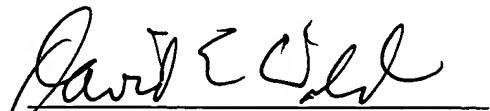
This paper is being filed within three months of the filing date of the application. Therefore, no fees are required. If a fee is deemed to be required, the Commissioner is hereby authorized to charge such fee to Deposit Account No. 19-0134.

In accordance with 37 C.F.R. §1.56, applicants wish to call the Examiner's attention to the references cited on the attached form(s) PTO-1449.

The listed references are of record in parent Application No. 09/722,784 filed November 27, 2000, and copies are available therein. However, applicants are willing to send copies of any or all of these references at the Examiner's request.

The Examiner is requested to consider the foregoing information in relation to this application and indicate that each reference was considered by returning a copy of the initialed PTO 1449 form(s).

Respectfully submitted,



David E. Wildman
Attorney for Applicants
Reg. No. 40,226

Novartis
Corporate Intellectual Property
One Health Plaza, Building 430
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Date: November 6, 2003

INFORMATION DISCLOSURE CITATION

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Sheet 1 of 7

ATTY. DOCKET NO.
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U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE
	AA	5,510,353	4/23/96	Giger et al.	514	300	
	AB	5,576,317	11/19/96	Gonsalves	514	231	
	AC	5,990,159	11/23/99	Meulemans et al.	514	469	
	AD	6,090,827	7/2000	Erickson et al.	514	338	
	AE	5,330,932	7/19/94	Tylers	514	214	
	AF	5,039,680	8/13/91	Imperato et al.	514	304	
	AG	5,198,459	3/30/93	Imperato et al.	514	397	
	AH	5,519,044	5/21/96	Imperato et al.	514	397	
	AI	5,929,059	7/27/99	Sanger et al.	514	171	
	AJ	5,098,889	3/24/92	Costall et al.	514	19	
	AK	5,859,065	1/12/99	Brandes	514	651	
	AL	5,877,189	3/2/99	McCullough et al.	514	327	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	OFFICE	CLASS	SUBCLASS	TRANSLATION YES <input type="checkbox"/> NO <input type="checkbox"/>
	AM	WO 92/00103	1/9/92	PCT			<input type="checkbox"/> <input type="checkbox"/>
	AN	WO 95/01803	1/19/95	PCT			<input type="checkbox"/> <input type="checkbox"/>
	AO	WO 97/29739	8/21/97	PCT			<input type="checkbox"/> <input type="checkbox"/>
	AP	WO 98/53802	12/3/98	PCT			<input type="checkbox"/> <input type="checkbox"/>
	AQ	WO 98/47481	10/29/98	PCT			<input type="checkbox"/> <input type="checkbox"/>

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent pages, Etc.)

AR	Shibata et al., Abstracts, P6.3.28, XII th International Congress of Pharmacology, <i>Molecular Mechanisms to Modern Medicine</i> , Montréal Canada, E3620: "A NOVEL 5-HT ₄ AGONIST AND 5-HT ₃ RECEPTOR ANTAGONIST, (July 24-29, 1994)
AS	Delvaux et al., A 496 AGA Abstract – Gastroenterology, Vol. 104, No. 4, Part 2 "Effect of the 5HT-3 Antagonist/5HT-4 Agonist Lintopride on Esophageal Motility in Healthy Volunteers. Manometric Study" (May 15-21, 1993)
AT	Funayama et al., Chemical Abstracts 1997:33987 (JP08283178, 10/29/96)

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AB	Quin et al., Br. J. Pharmacol., Vol. 108, No. 1, "Effects of cholinoreceptor and 5-hydroxytryptamine3 receptor antagonism on erythromycin-induced canine intestinal motility disruption and emesis.", pp. 44-49 (1993) - [93007406 EMBASE]
AC	Ciurzynska et al., J. Physiol. Pharmacol., Vol. 45. No. 4, "Gastric cytoprotective activity of endogenous 5-HT.", (1994) - [95037256 EMBASE]
AD	Jin et al., J. Pharmacol. Exper. Therap., Vol. 288, No. 1, "Propulsion in guinea pig colon induced by 5-hydroxy-tryptamine (HT) via 5-HT4 and 5HT3 receptors.", pp. 93-97 (1999)
AE	Hongo et al., Shin'yaku to Rinsho (J. New Remedies & Clinics), Vol. 36. No. 10, "Treatment of gastroesophageal reflux disease with cisapride. Combination therapy with H2 receptor.", pp. 1547-1552 (1987) - [880028559 JICST-EPlus]
AF	Galmiche et al., Gut, Vol. 29, No. 5, "Combined therapy with cisapride and cimetidine in severe reflux oesophagitis; a double blind controlled trial.", pp. 675-681 (1988) - [88284484 MEDLINE]
AG	Graham, Med. J. Australia, Vol. 150, p. 667, "Cisapride for severe non-ulcer dyspepsia, pseudoobstruction and constipation" - [89:7666 IPA]
AH	Tatsuta et al., Aliment. Pharmacol. Therap., Vol. 6, No. 2, Effect of treatment with cisapride alone or in combination with domperidone on gastric emptying and gastrointestinal symptoms in dyspeptic patients.", pp. 221-228 (April 1992) - [92288131 MEDLINE]
AI	Inauen et al, Gut, Vol. 34, No. 8, "Effects of ranitidine and cisapride on acid reflux and oesophageal motility in patients with reflux oesophagitis: a 24 hour ambulatory combined pH and manometry study.", pp. 1025-1031 (August 1993) - [94229536 MEDLINE]
AJ	Fehr, Scand. J. Gastroenterol. Suppl., Vol. 195, No., "Risk factors, co-medication, and concomitant diseases; their influence on the outcome of therapy with cisapride.", pp. 40-45; discuss. 45-46 (1993) [93296648 MEDLINE]
AK	Dallera et al., Clin. Terapeut., Vol. 144, No. 1, "Prokinetic activity and antral inflammation. Usefulness of cisapride combined with H2 antagonists in gastritis.", pp. 23-26 (January 1994) [944221881 MEDLINE]
AL	Thio et al., ASHP Annual Meeting, Vol. 52, "Evaluation of cisapride usage.". PP-104 (E) (REF) (June 1995) - [1995:252810 TOXLINE]
AM	Vigneri et al., N. Eng. J. Med., Vol. 333, No. 17, "A comparison of five maintenance therapies for reflux esophagitis [see comments].", pp. 1106-1110 (October 26, 1995)

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	AA	Dhasmana et al., Life Sciences, Vol. 53, "Gastrointestinal Effects of 5-Hydroxytryptamine and Related Drugs", pp. 1651-1561 (1993)
	AB	Kadowaki et al., The Journal of Pharmacology and Experimental Therapeutics, Vol. 266, No. 1, "Effect of FK1052, a Potent 5-Hydroxytryptamine ₃ and Hydroxytryptamine ₄ Receptor Dual Antagonist, on Colonic Function in Vivo", 74-80 (1993)
	AC	Lefebvre et al., Journal of Clinical Endocrinology and Metabolism., Vol. 80, No. 2, "The Serotonin-4 Receptor Agonist Cisapride and Angiotens-II Exert Additive Effects of Aldosterone Secretion in Normal Man", pp. 504-507, (1995)
	AD	Prous et al., Drugs of the Future, Vol. 19, No. 12, "Agent for Irritated Bowel Syndrome", pp. 1075-1077 (1994)
	AE	Schiantarelli et al., Pharmacological Research, Vol. 22, Supplemental 2, "The Prokinetic Properties of New Benzimidazolone Derivatives are Related to 5-HT ₄ Agonism", pp. 453-454 (1990)
	AF	Talley, Aliment Pharmacol. Ther., Vol. 6, "Review article: 5-Hydroxytryptamine Agonists and Antagonists in the Modulation of Gastrointestinal Motility and Sensation: Clinical Implications", pp. 273-289 (1992)
	AG	Tonini, Pharmacological Research, Vol. 33, No. 415, "Recent Advances in the Pharmacology of Gastrointestinal Prokinetics", pp. 217-226 (1996)
	AH	Drossman et al., Gastroenterology, Vol. 112, No. 6, "Irritable Bowel Syndrome: A Technical Review of Practice Guideline Development", pp. 2120-2137 (1997)
	AI	Castell et al., Practical Gastroenterology, "GERD: Management Algorithms for the Primary Care Physician and the Specialist", pp. 20-22, 26, 27, 32-34, 36-38, 42, 44 (February 1999)
	AJ	Sarna et al., Drug Development Molecular Targets for GI Diseases, Chapter 7, "5-HT ₃ /5-HT ₄ Receptors in Motility Disorders", pp. 177-202, September 1999
	AK	Symposium Workbook for the Digestive Disease Week Congress in Orlando, Florida on May 17, pp. 3, 4 and 9 (1999)
	AL	Giger et al., Derwent Abstracts, 89-310215/43 and English language Abstract (DE 38 10552 – filed 3/29/88)
	AM	Langtry et al., Drugs, 1998; 56(30):447-486
	AN	

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	AA	5,877,188	3/2/99	McCullough et al.	514	327	
	AB	5,137,893	8/11/92	Becker et al.,	514	293	
	AC	6,132,771	10/17/00	Depui et al.	424	468	
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	AM	WO 97/25065	7/17/97	PCT			<input type="checkbox"/>	<input type="checkbox"/>
	AN	WO 98/56364	12/17/98	PCT			<input type="checkbox"/>	<input type="checkbox"/>
	AO	WO 98/58647	12/30/98	PCT			<input type="checkbox"/>	<input type="checkbox"/>
	AP	2 200 046	7/27/88	United Kingdom			<input type="checkbox"/>	<input type="checkbox"/>
	AQ	0 814 840 B1	1/7/98	EP			<input type="checkbox"/>	<input type="checkbox"/>

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	AA	0 272 876	6/29/88	Europe			<input type="checkbox"/>	<input type="checkbox"/>
	AB	0 422 846 B1	4/17/91	Europe			<input type="checkbox"/>	<input type="checkbox"/>
	AC	2 236 528	4/10/91	United Kingdom			<input type="checkbox"/>	<input type="checkbox"/>
	AD	0 494 978 B1	7/22/92	Europe			<input type="checkbox"/>	<input type="checkbox"/>
	AE	WO 92/12716	8/6/92	PCT			<input type="checkbox"/>	<input type="checkbox"/>
	AF	0 916 346	5/19/99	Europe			<input type="checkbox"/>	<input type="checkbox"/>
	AG	WO 96/09818	4/4/96	PCT			<input type="checkbox"/>	<input type="checkbox"/>
	AH	WO 99/25353	5/27/99	PCT			<input type="checkbox"/>	<input type="checkbox"/>
	AI	WO 99/42095	8/26/99	PCT			<input type="checkbox"/>	<input type="checkbox"/>
	AJ	2,262,267	8/1/99	Canada			<input type="checkbox"/>	<input type="checkbox"/>
	AK	WO99/59593	11/25/99	PCT			<input type="checkbox"/>	<input type="checkbox"/>
	AL	WO99/61014	12/2/99	PCT			<input type="checkbox"/>	<input type="checkbox"/>
	AM	WO 00/51584	9/8/00	PCT			<input type="checkbox"/>	<input type="checkbox"/>
	AN	0 481 207	4/22/92	PCT			<input type="checkbox"/>	<input type="checkbox"/>
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	AT	2 325 161	11/18/98	United Kingdom			<input type="checkbox"/>	<input type="checkbox"/>
	AU	0 269 452	6/1/88	Europe			<input type="checkbox"/>	<input type="checkbox"/>
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	AW	2 193 633	2/17/88	United Kingdom			<input type="checkbox"/>	<input type="checkbox"/>
	AX	38 10552	10/19/89	Germany (see English Abstract)			<input type="checkbox"/>	<input type="checkbox"/>
	AY	WO 97/08144	3/6/97	PCT			<input type="checkbox"/>	<input type="checkbox"/>
	AZ	2,171,579	9/14/96	Canada			<input type="checkbox"/>	<input type="checkbox"/>

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AA	Darlington, Am. J. Health-Syst. Pharm, Vol. 54 "Hypoprothrombinemia induced by warfarin sodium and cisapride.", (1997) - [1997:75371 TOXLINE]
AB	Zix et al., Antimicrob. Agents Chemother., Vol. 41, No. 8, "Pharmacokinetics of sparfloxacin and interaction with cisapride and sucralfate.", pp. 1668-1672 (August 1997) [97400244 MEDLINE]
AC	Deneer et al., Br. J. Clin. Pharmacol, Vol. 45, No. 5, "Absorption kinetics of oral sotalol combined with cisapride and sublingual sotalol in healthy subjects.", pp. 485-490f (1998) -[CA 129:130833]
AD	Hill et al., Pediatrics, Vol. 101, No. 6, "Proarrhythmia associated with cisapride in children.", pp.1053-1056 (1998) - [1998:102586 TOXLINE]
AE	Yanagisawa et al., Nippon Shokakibyo Gakkai Zasshi. Jap.. J. Gastroenterol., Vol. 95, No. 9, "Effective treatment in combination with erythromycin and cisapride for chronic idiopathic intestinal pseudo-obstruction CIIP., pp. 1022-1026, (September 1998) - [1999002073 MEDLINE]
AF	Ueda et al., Aliment. Pharmacol. Therap., Vol. 8, No. 2, "Addition of cisapride shortens colonoscopy preparation with lavage in elderly patients.", pp. 209-214 (1994) - [1994:88298 TOXLINE]
AG	Kazami et al., Ther Res, Vol. 15(Supple. 2), S.456-S460, Polyethylene Glycol Electrolyte Lavage Solution (PEG-ELs) in Preparation for Colonoscopy. Aim at Reducing the Amount of PEGS-ELS in Effects of Combination Method with Cisapride.", (1994) - [940665284 JICST-E-Plus]
AH	Guller et al., Schweiz. Med. Wochenschr., Vol. 126, No. 31-32, "Colonic preparation with sodium phosphate. Prospective, randomized, placebo-controlled double blind study with various antiemetics. pp. 1352-1357 (1996) - [1996:118065 TOXLINE]
AI	Ministry of Defence, Porton Down (England), "Interactions between Pyridostigmine and the Anti-emetics Ondansetron and Granisetron." (1991) - [1996(02):566 NTIS]
AJ	King et al., Colloq. INSERM Vol. 223 (Mech. Control Emesis), "Possible potentiation of the emetic response to oral S(-) zacopride by various receptor ligands in the ferret.", pp. 217-226 (1992) - CA 117-245387]
AK	Dershawitz et al., Anesthesiol., Vol. 77, No. 3, Ondansetron does not affect alfentanil-induced ventilatory depression or sedation.", pp. 447-452 (1992) - [CA 117:184297]
AL	Jakala et al., Gen. Pharmacol., Vol. 24, No. 3, "The effects of tacrine and zacopride on the performance of adult rats in the working memory task.", pp. 675-679 (1993) - [93179260 EMBASE]
AM	Bailey et al. J. Psychopharmacol. (Oxford) Vol. 9, No. 2, " The 5-HT# antagonist ondansetron reduces gastrointestinal side effects induced by a specific serotonin re-uptake inhibitor in man.", pp.137-141 (1995)
AN	Herrstedt et al., J. Clin. Oncol., Vol. 15, No. 4, "Randomized, double-blind comparison of ondansetron versus ondansetron plus metoclopramide as antiemetic prophylaxis during platinum-based che

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AA	Ikoma, Ther Res, Vol. 18, No. 9, "The factor concerning the enterokinesis. Combined effect of 5HT3 receptor antagonist and muscarine receptor antagonist for chemical evil intention vomiting.", pp. 2735-2738 (1997) - [970961151 JICST-EPlus]
AB	Cook, N.Z. Vet. J., Vol. 46, No. 2, "Serotonergic and cholecystokinin antagonists change patterns of response in rats (Rattus norvegicus) to oral sodium monofluoroacetate.", pp. 76-78 (1998)
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AD	Aapro, Eur. J. Cancer, Vol. 27. No. 3. "Controlling emesis related to cancer therapy.", pp. 356-361 (1991) [91222685 MEDLINE]
AE	Latreill et al., Support. Care Cancer, Vol. 3, No. 5, "Dexamethasone improves the efficacy of granisetron in the first 24 h following high-dose cisplatin chemotherapy.", pp. 307-12 (September 1995) [96056723 MEDLINE]
AF	Akasaka et al., J. Clin. Therap. & Medicines, Vol. 11, No. 11, "Clinical Evaluation of 5-HT3 Antagonist Granisetron Monotherapy and Combination Therapy against Nausea and Vomiting by Anticancer Drugs. Multi-centered Comparative Study with Granisetron plus Methylprednisolone and Granisetron plus Metoclopramide.", pp. 2473-2485 [960069571 JICST-Eplus]
AG	Aranda et al., Tumori, Vol. 81, No. 6, "Prevention of highly emetogenic chemotherapy-induced vomiting: a double blind, randomized crossover study to compare pancopride (LAS 30451) and pancopride plus dexamethasone", pp. 432-434 (1995) [96397576 MEDLINE]
AH	Kris et al., J. Clin. Oncol., Vol. 15, No. 5, "Prevention of acute emesis in cancer patients following high-dose cisplatin with the combination of oral dolasetron and dexamethasone.", pp. 2135-2138 (1997) [97307013]
AI	Zeng et al., Zhonghua Zhongliu Zazhi, Vol. 20, No. 4., "Kangquan combined dexamethasone for prevention of vomiting after hepatic artery thrombochemotherapy." p. 263 (1998) [CA 130:119141]
AJ	Sorbe et al., Cancer, Vol. 83, No. 5, "A study evaluating the efficacy and tolerability of tropisetron in combination with dexamethasone in the prevention of delayed platinum-induced nausea and emesis.", pp. 1022-1032 (1998) [1998400633 MEDLINE]
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